

MAR 24 1998

TRADE SECRET

## 510 (k) SUMMARY

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92

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The assigned 510(k) number is: K980089

Submitted by: C. Kenneth French  
President  
Valley West, Inc.  
Hwy 6, North  
Meridian, Texas 76665

Telephone #: (254) 435-2306  
Facsimile #: (254) 435-2226

Date Prepared: 06 January 1998

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Establishment Registration Number: Valley West, Inc. is located at Hwy 6, North, Meridian, Texas 76665. We are registered with the Food and Drug Administration as Establishment Number 1645369.

Classification Name: Pressure Infusor for an IV bag  
21 CFR § 880.5420 (1997)

Laparoscope, Gynecologic and Accessories  
21 CFR § 884.1720 (1996)

Jet Lavage  
21 CFR § 880.5475 (1997)

Common/Usual Name: Pressurized Irrigation/Infiltration Pump

Proprietary Name: 3600 Pressure Infusor

Indication for Use: General surgical fluid irrigation and infiltration.

TRADE SECRET

## 510(k) SUMMARY (cont.)

**Device Description:** The principles of operation and technology incorporated in the 3600 Pressure Infusor are equivalent to pressurized irrigation systems, which use compressed nonflammable gases within a closed bladder (inflatable cuff to apply direct pressure externally to a bag of fluid for infusion of fluids.

**Substantial Equivalence Claim:** The principles of operation and technology incorporated in the Valley West, Inc. 3600 are similar to other irrigation devices with the function to pressurizing bags of fluid which the FDA has found to be substantially equivalent to pre-amendment devices as outlined below.

**Product:** MX820-5 Pressure Infusor 500cc / MX820-10 Pressure Infusor 1000cc  
**Manufacturer:** Medex, Inc.  
**510(k) Number:** K800560  
**Substantial Equivalence Date:** 29 April 1980

**Product:** Nezhat-Dorsey Hydro-Dissection Universal Bag Squeezer  
**Manufacturer:** Davol, Inc.  
**510(k) Number:** K953574  
**Substantial Equivalence Date:** 29 September 1995

**Product:** Automatic Surgical Irrigation Pump/Autocuff  
**Manufacturer:** Alton Dean Medical, Inc./Spartamed, Inc.  
**510(k) Number:** K922286  
**Substantial Equivalence Date:** Unknown

**Product:** Niagara Pump, 3.0 Liter High Volume  
**Manufacturer:** Cabot Medical Systems  
**510(k) Number:** K924530  
**Substantial Equivalence Date:** 05 February 1993

**Product:** Big Bag 3000  
**Manufacturer:** Byron Medical  
**510(k) Number:** K973133  
**Substantial Equivalence Date:** 10 September 1997

-end of summary-



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
3200 Corporate Boulevard  
Rockville MD 20850

MAR 24 1998

Mr. C. Kenneth French  
President  
Valley West, Incorporated  
Hwy. 6, North  
Meridian, Texas 76665

Re: K980089  
Trade Name: 3600 Pressure Infusor, Sigmacon 3600, Lapro  
Flow 3000  
Regulatory Class: II  
Product Code: FRN  
Dated: January 6, 1998  
Received: January 9, 1998

Dear Mr. French:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under section 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

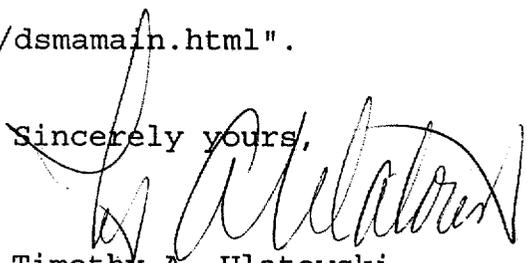
Page 2 - Mr. French

On August 16, 1993 the Final Rule for Device Tracking was published in the Federal Register, pages 43442-43455 (copy enclosed). Be advised that under Section 519(e) of the Act as amended by the Safe Medical Devices Act of 1990, FDA has identified the above device as a device which requires tracking. Because the device is subject to tracking, you are required to adopt a method of tracking that follows the devices through the distribution chain and then identifies and follows the patients who receive them. The specific requirements of the regulation are found in 21 CFR 821 as described in the August 16, 1993 Federal Register beginning on page 43447.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

  
Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control,  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

# Valley West, Inc.

510(k) Number (if known): K980089

Device Name: 3600 Pressure Infusor for General Fluid Irrigation/Infiltration

Indications for Use:

**The 3600 Pressure Infusor indications for use are general surgical fluid irrigation and infiltration.**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IS NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Roberta Cuente*

(Division Sign-Off)

Division of Dental, Infection Control,  
and General Hospital Devices

510(k) Number K980089

Prescription Use X  
(Per 21 CFR 801.109)

Over-the-Counter Use \_\_\_\_\_  
(Optional format 1-2-96)